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09/615,157	07/13/2000	Niraj A. Shah	ACS-52045	4747

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EXAMINER

BUI, VY Q

ART UNIT

PAPER NUMBER

3731

DATE MAILED: 11/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/615,157

Applicant(s)

SHAH ET AL.

Examiner

Vy Q. Bui

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

Art Unit: 3731

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 1-14, 16-22, 23, 25 and 26 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 6,391,044 to Yadav et al.

Regarding claims 1, 9, 14 and 22, Yadav discloses an embodiment of a filter delivery device in Figures 12 and 13 that includes all the limitations of claim 1. The device includes a guide wire (148) with tapered distal end (146), sheath (140), tubular shaft (142), and filtering assembly (144). The distal end of the sheath (140) is attached to the distal end (146) of the guide wire (148), while the proximal end of the sheath receives the filter. The distal tip (146) is interpreted to be part of the guide wire (148). The shaft (142) is positioned coaxially positioned around the guide wire (148), and as shown in Figs. 12-13, the shaft moves relative to the guide wire. The filter (144) is attached to the shaft (142). The filter is shown in the collapsed position in Figure 12, and is constricted in the sheath. Figure 13 illustrates the filter in an expanded position and released from the sheath.

Regarding claims 2, 10 and 23, the filter membrane (144) is attached to spines (152), or "splines" (column 8, line 17). Figure 3 illustrates that the splines of the filter assembly are annularly spaced.

Regarding claims 3, 5-6 and 25, the filter assembly is inherently self-deploying, because Yadav explains that the splines cause the filter to "release" as the sheath is removed (column 8, line 17). Yadav also teaches that the splines of the filter assembly can be made of nitinol, which is a shape memory, self-expanding material (column 6, line 22). Yadav also explains that the material of the filter membrane should be permeable to allow blood flow, but also be able to capture emboli (column 8, lines 50-52).

Regarding claim 4, the filter and shaft become disposed within the sheath simultaneously as the sheath is moved proximally (Fig. 12).

Regarding claim 7, the tubular shaft does comprise a recess that houses the splines in the unexpanded position (Fig. 12-13).

Regarding claims 8 and 12, the sheath can be made of a polymeric material (column 8, line 46), which is inherently flexible.

Regarding claims 11, 13, 16 and 26, Yadav explains that the tubular shaft may be made of polymer, stainless steel, or **nitinol** (nickel titanium alloy) (column 5, lines 19-22). Nitinol is capable of withstanding buckling. The tubular shaft is inherently a "hypotube", since it is sized for hypodermic use.

Regarding claims 17-21, YADAV discloses substantially all structural limitations of the device as claimed and a method comprising substantially steps for using the

Art Unit: 3731

device to treat a diseased blood vessel (see claims 15-19, YADAV).

***Claim Rejections -35 USC ~ 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yadav in view of US Patent No. 5,108,419 to Reger et al.

Yadav includes all the limitations of claim 24, except for a plurality of recesses to receive the splines when the filter assembly is collapsed. Yadav does include a continuous recess in the shaft for receiving the splines, but fails to form a *plurality* of recesses. Reger discloses a filter device with splines, as shown in Figure 14. Reger teaches that a tubular shaft (180) can have a structure for receiving splines (184) that is formed as a plurality of recesses (182), as shown in Figure 17. It would have been obvious to one of ordinary skill in the art at the time the invention was made to form the spline-receiving structure of Yadav as a plurality of recesses, as taught by Reger, as this is just a substitute for the singular recess of Yadav.

***Response to Amendment***

The amendment filed on 8/8/2003 under 37 CFR 1.131 has been considered but is ineffective to overcome the YADAV reference.

YADAV reference (Figs. 12-13) clearly shows steerable guide wire (148) having tapered distal tip (146) for easy navigation of the guide wire (148) in a tortuous blood vessel of a patient. Sheath (140) is attached to guide wire distal tip (146) so as to house filter assembly (152) (see Figs. 12-13, YADAV) during navigation of the guide wire (148) before deployment of filter (152). YADAV reference labels guide wire (148) as movable core and tubular shaft member (142) as guide wire (col. 8, lines 4-18), however, the labels/names/terms used in YADAV reference different from the labels/names/terms used in the instant invention for equivalent structural elements do not mean that YADAV teaches away from the instant claimed invention, but only to illustrate that the same invention/device/method of using a device can be described and claimed in different languages/phraseology as desired by an applicant. An ordinary skill in the art can easily recognizes that the teaching of YADAV and the claimed invention are essentially the same.

Since the claimed invention has not been clearly defined over the YADAV reference, the invention as claimed is not patentable over YADAV and other reference as mentioned above.

**Conclusion**

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vy Q. Bui whose telephone number is 703-306-3420. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J Milano can be reached on 703-308-2496. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.



VQB

11/20/2003.